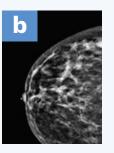
BREAST DENSITY CATEGORIES



Category a Almost entirely fatty breasts



Category **b** Scattered areas of dense tissue



Category c Increased presence of dense tissue: May hide small masses on mammography



Category d Mostly dense tissue in breasts: May hide masses of all sizes on mammography

Ask your [Site name] Healthcare Team About SoftVue™ Today!



[site-email@email.org] [888.888.8888]

> [Site Name] [Site Address] [Site City, State, Zip]





FACILITY LOGO HERE



If you have dense breasts, **SoftVue™** is the screening **SOLUTION for YOU!** SoftVue™ 750-00191 Rev 0.01 8/12/2022 10:13:15 AM

dense breasts.

Do you have dense breasts?

Having dense breasts increases

your cancer risk & mammography misses almost 50% of cancer in





Breasts are made up of different types of tissue and fat. When there is more tissue present than fat, the breast is considered dense.

Mammography's accuracy is limited in dense breasts because both breast tissue and cancers appear white on mammography which means cancer can hide in dense breast tissue on x-ray, even with the advancements of digital and 3D mammography.

Nearly 50% of all women have dense breast tissue, and while it occurs more frequently in younger women, women of any age can have it.

Not only is cancer difficult to detect with mammography in dense breast tissue, having dense breasts increases your risk of developing breast cancer. Since dense breast tissue can increase your cancer risk, it's important to know your breast density. The amount of tissue in your breasts determines your density category.

There are four categories of density, ranging from completely fatty to extremely dense. You can't actually feel how dense your breasts are, but mammograms can determine your breast



density. If you fall into breast density category

c or d it is recommended to get supplemental

ultrasound in addition mammography to effectively

screen for breast cancer.

Why SoftVue™?

SoftVue™ was invented and FDA approved to address the problem associated with imaging dense breasts. SoftVue is based on ultrasound technology, meaning it operates with the same kind of harmless soundwaves used to image babies in pregnant women. Cancers are easier to detect on ultrasound because cancer appears dark on ultrasound images, in contrast to white breast tissue, making it easier for a radiologist to find cancers in women with dense breasts compared to screening with mammography alone.

The exam is conducted without radiation or compression. More than 90% of women who have experienced the SoftVue™ exam rate it as one of the more comfortable breast imaging exams they have experienced and would recommend it to other women.

THE SOFTVUE™ EXPERIENCE

SoftVue™ uses a circular imaging ring that surrounds the breast while it is immersed in warm water. The imaging ring emits soundwaves that travel through and around the breast capturing images every 2 millimeters as it moves from the nipple to the chest wall.

The SoftVue™ experience is easy and comfortable, with no compression or radiation.

- 1. You relax on your stomach, with one breast immersed in warm water
- 2. A soft gel pad engages with the nipple sitting on a platform under the water to center and support it during the imaging process
- 3. The imaging ring is raised to make gentle contact with the area of the chest surrounding the breast to ensure full coverage of the breast during the exam
- **4.** The technologist then starts the exam and the imaging ring moves from the nipple to the chest wall creating a series of 3D cross-section pictures
- **5.** Upon completion of imaging the first breast, the second breast is imaged using the same process





After both breasts have been scanned, the radiologist physician reviews the SoftVue™ images alongside your mammography images to determine if any areas need further examination.

Frequently Asked Questions

Will my name and personal information be provided to researchers using my samples?

No. Your personal information will not be provided to anyone. We may ask your permission to use information about your care (what type of treatment was used and how you responded to treatment) but it will never be associated with your name.

If I decide not to participate in this program, will I get the same care from my physicians?

Yes. This is a completely optional study. Your physicians will not be informed of your participation unless you choose to tell them.

How does my participation in the biobank help research?

Biospecimens help researchers discover new and better ways to treat cancer. Your specimens will give them the opportunity to study your cancer as well as that of others to make this progress in the development of cancer care.

Thank you!

On behalf of Karmanos scientific researchers and cancer patients who will benefit from research at Karmanos, we thank you for taking the time to consider donating your tissue, blood or bone marrow to the Biobank.

Please visit out our website for information regarding scientific discoveries that were made using biospecimens from Karmanos' Biobank at www.karmanos.org/biobank.

Questions?

If you have any questions or concerns, please call the Biobank at 313-576-9794, or email biobank@karmanos.org.





Wayne State University

4100 John R. Detroit, MI 48201

Karmanos.org

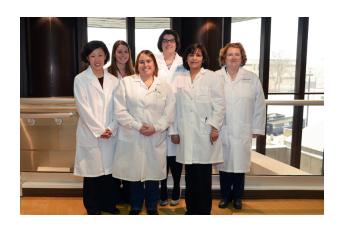
Biobank Services



The future of cancer care begins with you!



Wayne State University



About Karmanos Cancer Institute Biobanking Services

Karmanos researchers are dedicated to learning more about cancer to improve cancer diagnoses, treatments and preventative care for patients. Much of this research is done using human biospecimens, such as blood, discarded tissue or bone marrow.

Using these samples, researchers are able to study how genes affect cancer growth and respond to treatment. This research brings researchers closer to the development of new drugs or tests for diagnosis and treatment of different cancers and diseases. By participating in this protocol, you will be making a valuable contribution to the future of cancer care.

Eligibility

All patients seen at Karmanos and McLaren Healthcare Corporation will be eligible to participate.

Participating in the Karmanos Biobank

If you choose to participate in contributing to Karmanos' Biobank, you will be given a consent form during the office visit with your physician. This form contains more information about the Biobank and at this time you will have an opportunity to ask any questions you may have. You will be required to sign the consent form giving Karmanos your informed consent for participation in the Biobank.

If you have any questions or concerns at a later date, please call the Biobank at 313-576-9794 and ask speak to one of our Biobank consenters. They will be happy to answer your questions and provide you with more information.

At your next scheduled laboratory visit, you may donate extra tubes of blood (no more than 2 tsp) that will be collected by Biobank staff and processed for storage.

If you have surgery and there is any tissue removed that is not needed for diagnosis and future treatment, the Biobank staff will collect and process the tissue for storage.





If you have bone marrow collected for a clinical procedure, an extra tube (1 tsp) may be collected by the Biobank staff and processed for storage.

Withdrawl

If you would like to withdraw your permission to use your blood, tissue and/ or bone marrow, you can do so at any time. Please call the phone number in your copy of the consent form and we will destroy your biospecimens immediately.

Frequently Asked Questions

Will I need an extra blood draw or will more tissue be removed during surgery if I consent to this program?

No. We will obtain extra tubes of blood at your next scheduled blood draw. We will use tissue only if there is any extra beyond what the doctors need (which is normally discarded).

Will my samples be stored in a safe location?

Yes. Your samples will be stored in a locked room in a locked storage unit. The samples will be labeled with a random set of numbers that will not contain any personal information.

THE SOLUTION

FOR DENSE BREAST SCREENING











A SYNTHESIS OF INNOVATIONS

SoftVue™ is an unparalleled 3D whole breast ultrasound tomography system positioned as a breakthrough, first-ever in medical imaging device, delivering a transformational approach to breast cancer detection for individuals with dense breasts.



Utilizing **TRIPLE ACOUSTIC DETECTION**, or **TriAD™**, technology, SoftVue™ offers 3X the imaging power compared to standard ultrasound.









Patented **circular-array transducer** and **Sequr™ Breast Interface** provide the basis for the scanning process and image acquisition



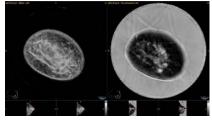


Three sound signals, Reflection, Sound Speed and Attenuation, are collected during the scan and reconstructed into **four image sequences** for interpretation





Presented in the **coronal plane** allowing radiologists to scroll through the entire volume of the breast



UNPARALLELED PATIENT E X P E R I E N C E

The SoftVue[™] exam not only increases cancer detection in women with dense breasts, but also offers a patient experience that is unmatched by any other breast imaging modality. In fact, **95% of women** who experience a SoftVue[™] exam said they would recommend it to other women.

Utilizing a warm water bath, the exam is conducted with **NO COMPRESSION** or **RADIATION**.



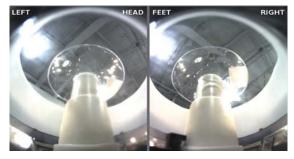
PATIENT POSITIONING

- Warm water coupling agent
- Memory-foam table-top
- 2-3 minute scan per breast



ENGAGE WITH SEQUR™ BREAST INTERFACE

- Acoustically transparent gel
- Engaged with gentle vacuum
- Elongates and stabilizes breasts
- Single use device



CUSTOMIZE & VISUALIZE

- Customizable transducer position
- Dual camera visualization
- Accommodates patient shape
- Nipple to chest wall coverage



SCAN ACTIVATION

- Push-start fully automated operation
- 2048 sequenced elements
- TriAD™ Technology
- · Image output to coronal plane

EFFICIENT EXAM W O R K F L O W

The SoftVue[™] exam is private and discreet as the breast is not openly seen during the scanning process, and is faster than standard hand-held ultrasound, with the **scan taking 2-3 minutes** on average per breast.

STEP ONE



The operator scans a new Sequr™ Breast Interface to initiate the exam process.

STEP THREE



The Sequr™ Breast Interface engages with the front of the breast to center, shape, and steady it during the image acquisition process.

STEP TWO



Patient lies prone on the SoftVue™ table lowering one breast into the warm water imaging chamber.

STEP FOUR



With one touch, the scan is activated and the ring transducer moves along the breast, imaging all levels.

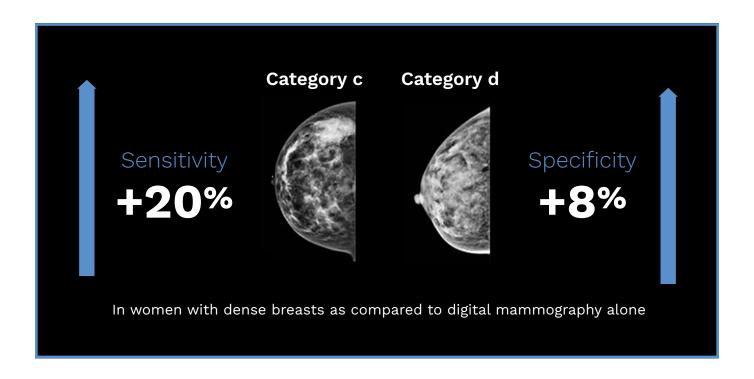
INCREASING CANCER DETECTION

For too long, women with dense breasts have been at a disadvantage with breast cancer screening. In fact, mammography misses almost half of cancers in women with dense breasts and there is a lack of efficient and effective supplementary screening options available. SoftVue's revolutionary imaging power eliminates this disadvantage.

SoftVue™, in combination with mammography, has proven to increase cancer detection and potentially reduce call backs and false positives.

Data analysis following the retrospective reader study in which independent radiologists interpreted dense breast patient mammograms in conjunction with their SoftVue™ exam showed the following:

With the Addition of SoftVue™



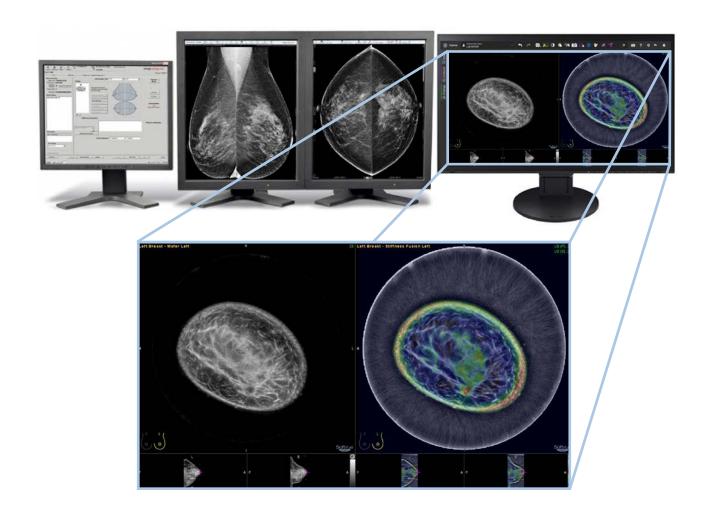
E A S Y T O U S E S O F T W A R E

SoftVue™ Image Review Software

FLEXIBLE, ADAPTABLE, PORTABLE AND EFFICIENT

SoftVue™ offers a secure, user-friendly digital viewing environment offering customizable image view ports and short-cut keys to accommodate radiologist preferences during image interpretation.

- SoftVue™ can utilize existing workstation
- · Offers volumetric review of the breast
- Provides for correlation to other imaging modalities
- · Presents an efficient reading workflow
- Supports multi-user and multi-location connectivity



CORONAL PLANE PRESENTATION

Following the SoftVue™ exam, the reflection, sound speed and attenuation signals are reconstructed into four image sequences for radiologist review on the SoftVue™ Image Review Software. The tomographic coronal image presentation delivers an unrivaled view of the structure of breast tissue that assists physicians in distinguishing normal tissue from areas of concern.

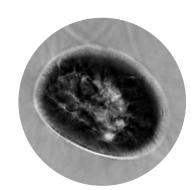
The **Wafer**, **Sound Speed**, **Reflection** and **Stiffness Fusion** volumetric image sequences are presented for interpretation and comparison with an individual's mammogram.

DETECTION SEQUENCES



Wafer

Sound Speed in combination with the Reflection lowers the visibility of fat and to enhance the remaining tissues.



Sound Speed

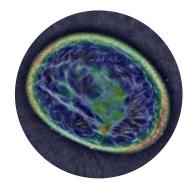
Depicts change in Speed of Sound moving through breast tissue.

CHARACTERIZATION SEQUENCES



Reflection

Dynamic display of breast tissue structure and potential masses.



Stiffness Fusion

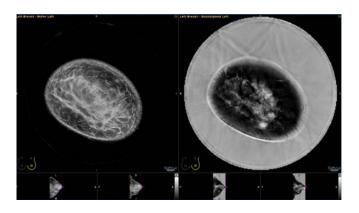
Attenuation in combination with sound speed provides relative differences in tissue stiffness.

COMPREHENSIVE IMAGE INTERPRETATION

SoftVue™ Image Review

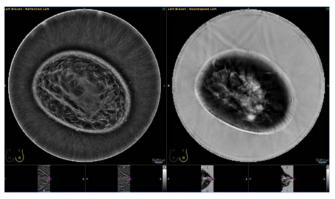
The SoftVue™ Image Review Software offers an efficient reading work flow with the workstation positioned next to the mammography viewing station, allowing physicians to quickly compare areas of concern identified on either modality.

SOFTVUE™ WORKFLOW



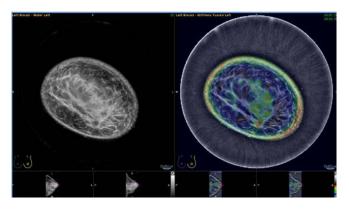
STEP ONE

- Review SoftVue[™] Wafer and Sound Speed sequences in conjunction with mammography images
- Look for area of concern on these two sequences



STEP TWO

 Advance to SoftVue[™] Reflection and Sound Speed sequences if area of concern is identified on previous sequences



STEP THREE

 If area of concern is confirmed, view Stiffness Fusion sequence to gauge relative stiffness of area

INTEGRATED TRAINING

To ensure confidence in adopting this new technology, Delphinus offers a comprehensive and integrated training program for radiologists learning to interpret SoftVue™ images and operators responsible for conducting the SoftVue™ scan.

RADIOLOGIST IMAGE INTERPRETATION TRAINING PROGRAM

Virtual Training

- 10 video modules
- · Average 12.5 minutes per module
- Presented by leading breast imaging radiologists
- Training assessment offered after each module to reinforce training concepts

In-Person Training

- 8-hour training session offered at healthcare facility or Delphinus' education facility
- Variety of SoftVue[™] cases presented incorporating both group review and prospective review setting
- Offers organic case discussion and one-on-one training opportunities



OPERATOR TRAINING PROGRAM

*Approved by the ASRT for 21.25 Category A continuing education credits

Virtual Training

- 2 video modules
- Provides overview of the SoftVue™ scanning procedure, cleaning and maintenance
- Training assessment offered after the modules to reinforce training concepts

In-Person Training

- Conducted over three days with a maximum of two trainees at healthcare facility with newly installed SoftVue™ system
- Training will cover the SoftVue[™] Operator
 Training Guide and SoftVue[™] User Manual
- Each trainee will scan a minimum of 8 volunteers to be recruited by healthcare facility



C O D E S F O R REIMBURSEMENT

REIMBURSEMENT

SoftVue[™] is a whole breast ultrasound exam and utilizes **CPT codes 76641** and **76642**. Use modifier 50 to report bilateral procedures performed during the same operative session by the same physician.

Code	Description
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; Complete
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; Limited



ASSURANCE AND TECHNICAL SERVICE

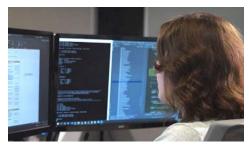
Each SoftVue™ 3D Whole Breast Ultrasound Tomography System is built with the highest quality standards achieving ISO compliance in important areas of quality management, IT security, service quality, and environmental impact.

We offer each client a complimentary one year membership in the **SoftVue™ Assurance Program**. This is our guarantee to provide efficient and professional service and includes:

- Regular system maintenance
- Installation of software and hardware upgrades
- SoftVue™ Image Review Software license
- SoftVue[™] system warranty

Extended programs are available to begin your first year to ensure you continue receiving these exclusive benefits:

- Complimentary system compliance upgrades
- Extended coverage hours for all service requests
- Extended Softvue[™] system warranty
- Continue preventative maintenance services







$S O F T V U E^{*}$ T E S T I M O N I A L S

"The SoftVue™ experience was painless, relaxing and easy!"

SoftVue™ research participant Rochester, NY

"A spa-like experience compared to a mammogram."

SoftVue™ research participant Miami, FL

"It was less traumatic, less invasive, it was simply laying down on my stomach and allowing myself to float in a small pool of water."

Esther Galvez-Dopico
Detroit, MI

"Could have fallen asleep."

SoftVue™ research participant Rochester, NY

"So nice to be relaxed and not feel pain."

SoftVue™ research participant Dearborn, MI "The experience was private and calming and I felt very comfortable."

> SoftVue™ research participant Pittsburgh, PA

"There is no compression, it is very comfortable and relaxing, and not to mention very fast and easy to do."

> Vivian Linke Detroit, MI

"A much (million times) better experience than the regular mammogram."

SoftVue™ research participant Appleton, WI

"This was 100 percent more pleasant and much less stressful for me."

SoftVue™ research participant Los Angeles, CA "It was by far the best breast health exam ever. I would never skip or postpone a breast exam using SoftVue™."

> SoftVue™ research participant Savannah. GA



"Exactly what is needed in breast cancer screening."

SoftVue™ research participant Dearborn, MI



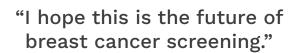
"Will recommend to other women."

SoftVue™ research participant Miami, FL



"Pain-free and no radiation, so I was happy about those two things!"

> Gail Kucinski Detroit, MI



SoftVue™ research participant Los Angeles, CA



THE SOLUTION FOR DENSE BREAST SCREENING



GLOBAL HEADQUARTERS 45525 Grand River Avenue Novi, MI USA

delphinusmt.com











3D WHOLE BREAST ULTRASOUND TOMOGRAPHY

IMPLEMENTATION GUIDE





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BUILDING YOUR DENSE BREAST SCREENING PROGRAM

Current research estimates that over 40% of women in the US have dense breasts and that mammography misses up to 50% of cancers in women with dense breasts. In an effort to curb the cancer screening disparity for women with dense breasts, FDA issued updated Mammography Quality Standards Act (MQSA) guidelines in March 2023 requiring facilities that are MQSA certified to:

- Notify women of their breast density following their annual mammogram.
- Include standard language provided by FDA that will note the limitations of mammography for women with dense breasts.
- Encourage discussion of supplemental screening between the patient and physician

With the adoption of SoftVue 3D Whole Breast Ultrasound Tomography, you are the LEADER in the market with a dedicated Dense Breast Screening Program that offers the first FDA PMA approved ultrasound-based imaging modality that increases sensitivity, improves specificity with the indication for same-day screening as mammography.

Now, you have the screening **SOLUTION that** will set your practice apart from the competition with 95% of women who have experienced SoftVue indicating they would recommend it to other women. Delphinus offers a comprehensive planning guide geared toward both administrative and clinical audiences. It will be critical to your success to manage your new SoftVue investment as an important program that will bolster your current women's health services and support your current cancer program with an increase in cancer detection through enhanced SoftVue screenings.

Develop Your Strategy

A successful dense breast screening program begins with a comprehensive business plan that includes technical, clinical and economical elements. Establishing clear objectives, measurable goals and tracking achievement of metrics will set your team on the path to success.

Questions to Consider

- How does the Dense Breast Screening program align with your organizational mission?
- How does the program compliment or support existing goals?
- What metrics will be used to determine program success?
- Increased screening volume resulting in increased revenue?
- Successful workflow integration?
- Increased market share?
- Pulling patients from competitve centers?

Establish Your Budget

- Determine information technology and software costs to accommodate SoftVue.
- Allocate financial resources for the Sequr Breast Interface consumable & cleaning supplies. marketing collateral to promote your program.

Coordinate Internal Operations

Identifying key departments and team members are integral to the successful implementation of a SoftVue dense breast screening program. It is recommended to organize a "Dense Breast Screening Program Committee" with clearly defined roles, targets, tasks and timelines. If there are potential delays the team should align on how to address the concern while continuing to move the project forward in other areas when possible

Committee Roles to Consider

- Billing representative(s) to provide guidance on insurance reimbursement.
- Breast Center Manager to support coordination and clinical execution of the program.
- Breast Radiologist championing the SoftVue program and integration into clinic workflow.
- C-Suite/Administrative Leaders to provide support and accountability for program success.
- **Dense Breast Screening Coordinator(s)** responsible for coordinating clinical workflow and scheduling of SoftVue exams in combination with the patient's mammogram.
- Facilities Coordinator to oversee room preparations and SoftVue installation.
- IT Project Manager to assist with the implementation of the SoftVue Image Review Software and PACS integration.
- **Project Manager** who is responsible for the oversight of the project to ensure the project moves forward on-time and on-budget.
- Marketing Director to develop a communications and marketing strategy
- SoftVue Operator to receive training on performing SoftVue scans and provide insight in

Promote! Promote! Promote!

To increase visibility of your new SoftVue dense breast screening program the Delphinus Marketing Team offers a suite of promotional materials and guidance for patients and physicians.

Co-branded Marketing Collateral

Patient Focused Materials

- Tri-fold brochures, posters, flyers, postcards
- Reminder letter text and educational inserts
- SoftVue educational videos, and co-branded video advertisements
- Website content, and newsletter copy

Physician Focused Materials

- Physician outreach letter
- SoftVue promotional flyer
- SoftVue overview educational presentation
- Dense Breast Screening promotional video

Public Relations & Media Resources

- Press release template for SoftVue installation & program launch
- SoftVue media messaging talking points
- Delphinus & SoftVue FAQ

Promote! Promote! Promote!

SoftVue is a unique technology that offers clinicians the diagnostic confidence and patients the unmatched comfort that has been missing in dense breast imaging. With a 20% increase in cancer detection in combination with mammography and 95% recommendation rate from women who have experienced the exam, SoftVue will set your breast center apart from the competition.

It is recommended that you begin announcing the addition of SoftVue to your breast center as early as possible to build your patient volume prior to launching your SoftVue dense breast screening program. The key to success is to have a full patient schedule with the launch your program.

Successful Communications Strategy

- Add a web page on your internal & external websites dedicated to SoftVue and dense breast screening.
- Develop an internal communications plan utilizing internal media channels.
- Plan and execute external media campaign using PR, social media and launch events to draw attention to your new SoftVue dense breast screening program.
- Notify and educate referring physicians and internal physicians about the addition of SoftVue to your breast center.
- Build a SoftVue awareness campaign using social media, email and direct mail pieces targeted at women in your community to increase referrals.
- Target promotion of SoftVue around women focused months or dates,
- Set targets and metrics to determine success of your SoftVue promotion efforts.

OPERATIONAL CONSIDERATIONS

Create a Vision

Every launch of the SoftVue dense breast screening program begins with a clear vision of how it will benefit patients as well as the breast center. A clear vision includes identification of team roles, clinic workflow and success metrics. It is also important to communicate your program goals with internal and external stakeholders to ensure accountability for the success of the program.

When?

This vision should be developed and ready to be communicated by the initial SoftVue dense breast screening program kick-off meeting. Document your vision visually, such as on a poster.

Who?

The members of the SoftVue dense breast screening program including, radiologists, operators & administrative staff.

Why?

To keep the team engaged and enthused about the new program during the installation and implementation process.

How?

- Work with your Delphinus account representatives to identify inspirational, mission-based messaging to engage your team and keep them focused on the successful implementation & launch of SoftVue at your facility.
- Establish a project implementation plan with the committee to keep on schedule. Following the launch of SoftVue, host quarterly business reviews with the committee and Delphinus.

OPERATIONAL CONSIDERATIONS

Establish a Successful Workflow

Identifying members of your breast center team that will be trained as SoftVue operators and image reviewers is the first step in developing your dense breast screening workflow. As SoftVue is a new technology it will take time to become proficient in executing an exam or reviewing images, which is why it is requested to limit the number of radiologists and operators trained on SoftVue to two individuals for each role.

Training

- Operators 1 online training module is used to familiarize the users with concepts and procedures for conducting a SoftVue scan. Following the completion of online training the users will engage in a three-day, hands-on training session that will include scanning of human volunteers.
- Radiologists 10 online training modules will introduce the reviewers to SoftVue image lesion characteristics and reading protocol and will be followed one day of instructor lead, in-person image review to ensure proficiency in SoftVue image interpretation.

Identifying your dense breast patients

- The qualified SoftVue patient is a **women with BIRADS c or d density**, is due for her annual mammogram, has an **order for supplemental imaging**, specifically ultrasound.
- Work with your scheduling team to identify dense breast patients in current schedule or from previous years that may be eligible for SoftVue and contact them a head of time to offer SoftVue with their annual mammogram.
- Reach out to your referring providers and inform them of SoftVue for dense breast imaging at your facility to increase your patient volume.

After identifying your patients, it is critical to establish a successful clinical workflow. **SoftVue scan** plus reconstruction time averages 30-45 minutes depending on breast size. You may want to start with 5 to 8 slots per day to help better estimate the timing for scheduling with the goal to scan 12 per day by the end of the first month of clinical SoftVue use.

IMPLEMENTATION SUMMARY

Our Commitment to You

SoftVue is the answer to the technology gap for screening women with dense breasts and the Delphinus Team is excited to be on this implementation journey with you. We hope this guide sets you and your clinical team on the path to success. As you progress through the launch of your SoftVue Program return to this guide to ensure you are following the best practices to achieve program goals and improve patient care and your.

We are here to...

- Coordinate and lead the initial kick-off meeting to ensure all goals, tasks and deadlines are clearly defined and assigned to the appropriate team member.
- Take the lead in installation planning for SoftVue and clinical training.
- Participate in the Dense Breast Screening Program Committee, as requested.
- Work with your team to identify SoftVue Operators and Radiologists.
- Help with clinical workflow and image review workflow planning within your breast center.
- Offer image review support as radiologists begin executing clinical SoftVue interpretation.
- Conduct scan support as SoftVue operators being executing Clinical SoftVue exams.
- Support your marketing team in execution of SoftVue launch campaigns and events.
- Partner with your team to ensure technical workflow via PACS is seemless
- Work with the entire team to ensure the success of your SoftVue screening program.

You have our support

Our dedicated and expert account management, marketing, technical service and clinical training teams will work with you hand-in-hand to ensure a successful integration of SoftVue into your practice. Do not hesitate to contact us pre-and post-installation of your SoftVue 3D Whole Breast Ultrasound Tomography System, we are always here to assist and lend a hand to our clinical partners.





GLOBAL HEADQUARTERS 45525 Grand River Avenue Novi, MI USA delphinusmt.com

